

IN THE CLAIMS

Kindly **Cancel** in this application claims 2-42 before calculating the filing fee. (At least one original independent claim must be retained for filing purposes).

Please **Add** claims 43-54 . (**Claims added have been re-numbered** consecutively following the highest numbered original claims).

MARKED-UP VERSION OF PENDING CLAIMS

1. A method of removing a pathogen from a mixture containing a compound and the pathogen, the method comprising:

- (a) placing the compound and pathogen in a first solvent stream, the first solvent stream being separated from a second solvent stream by a selective membrane having a defined pore size;
- (b) selecting a buffer for the first solvent stream having a required pH;
- (c) applying an electric potential across the first and second solvent streams, wherein the application of such electric potential causes movement of at least a portion of the compound through the membrane into the second solvent stream while the pathogen is substantially retained in the first solvent stream, or if entering the membrane, being substantially prevented from entering the second solvent stream and wherein substantially all transmembrane migration of the compound is initiated by application of the electric potential;
- (d) optionally, periodically stopping and reversing the electric potential to cause the movement of any pathogens having entered the membrane to move back into the first solvent stream, wherein substantially not causing any compounds that have entered the second solvent stream to re-enter the first solvent stream; and

(e) maintaining step (c), and optional step (d) if used, until the second solvent stream contains the desired purity of the compound.

2. (Canceled) A method of removing a pathogen from a mixture containing a compound and pathogen, the method comprising:

(a) placing the compound and the pathogen in a first solvent stream, the first solvent stream being separated from a second solvent stream by a selective membrane having a defined pore size;

(b) selecting a buffer for the first solvent stream having a required pH;

(c) applying an electric potential across the first and second solvent streams, wherein the application of such electric potential causes movement of at least a portion of the pathogen through the membrane into the second solvent stream while the compound is substantially retained in the first solvent stream, or if entering the membrane, being substantially prevented from entering the second solvent stream and wherein substantially all transmembrane migration of the pathogen is initiated by application of the electric potential;

(d) optionally, periodically stopping and reversing the electric potential to cause the movement of any compound having entered the membrane to move back into the first solvent stream, wherein substantially not causing any pathogens that have entered the second solvent stream to re-enter the first solvent stream; and

(e) maintaining step (c), and optional step (d) if used, until the first solvent stream contains the desired purity of the compound.

3. (Canceled) The method according to claim 1 wherein the compound is selected from the group consisting of blood proteins, immunogloblins, recombinant proteins, and combinations thereof.
4. (Canceled) The method according to claim 1 wherein the pathogen is selected from the group consisting of viruses, bacteria, prions, and combinations thereof.
5. (Canceled) The method according to claim 1 wherein the pathogen is a virus.
6. (Canceled) The method according to claim 1 wherein the pathogen is a bacterium.
7. (Canceled) The method according to claim 1 wherein the pathogen is a prion.
8. (Canceled) The method according to claim 1 or 2 wherein the biological contaminant is selected from the group consisting of lipopolysaccharide, toxin, and endotoxin.
9. (Canceled) The method according to claim 1 wherein the solvent for the first solvent stream has a pH lower than the isoelectric point of the compound.
10. (Canceled) The method according to claim 1 wherein the selective membrane has a molecular mass cut-off between about 3 and about 1000kDa.

11. (Canceled) The method according to claim 1 wherein the electric potential is up to 300 volts.
12. (Canceled) The method according to claim 1 or 2 wherein the biological contaminant is collected or removed from the first stream or second stream.
13. (Canceled) The method according to claim 1 wherein the selective membrane has a molecular mass cut-off close to the apparent molecular mass of the compound.
14. (Canceled) Use of Gradiflow in the purification or separation of biomolecule from a biological contaminant.
15. (Canceled) A compound and solvent stream substantially free from pathogens purified by the method according to claim 1.
16. (Canceled) Use of biomolecule according to claim 15 in medical and veterinary applications.
17. (Canceled) The method according to claim 1 wherein the solvent for the first solvent stream has a pH at about the isoelectric point of the compound.
18. (Canceled) The method according to claim 1 wherein the solvent for the first solvent stream has a pH above the isoelectric point of the compound.

19. (Canceled) The method according to claim 1 wherein the membrane has a molecular mass cut-off of at least about 3 kDa.
20. (Canceled) The method according to claim 1 wherein the compound is collected or removed from the second solvent stream.
21. (Canceled) The method according to claim 1 wherein step (e) results in the compound being substantially free of any pathogens.
22. (Canceled) The method according to claim 2 wherein the pathogen is selected from the group consisting of viruses, bacteria, prions, and combinations thereof.
23. (Canceled) The method according to claim 22 wherein the pathogen is a virus.
24. (Canceled) The method according to claim 22 wherein the pathogen is a bacterium.
25. (Canceled) The method according to claim 22 wherein the pathogen is a prion.
26. (Canceled) The method according to claim 2 wherein the compound is selected from the group consisting of blood proteins, immunoglobulins, recombinant proteins, and combinations thereof.

27. (Canceled) The method according to claim 2 wherein the solvent for the first solvent stream has a pH lower than the isoelectric point of the pathogen.

28. (Canceled) The method according to claim 2 wherein the solvent for the first solvent stream has a pH at about the isoelectric point of the pathogen.

29. (Canceled) The method according to claim 2 wherein the solvent for the first solvent stream has a pH above the isoelectric point of the pathogen.

30. (Canceled) The method according to claim 2 wherein the membrane has a molecular mass cut-off close to the apparent molecular mass of the pathogen.

31. (Canceled) The method according to claim 2 wherein the membrane has a molecular mass cut-off of at least about 3 kDa.

32. (Canceled) The method according to claim 31 wherein the membrane has a molecular mass cut-off of between 3 and 1000 kDa.

33. (Canceled) The method according to claim 2 wherein the electric potential applied is up to about 300 volts.

34. (Canceled) The method according to claim 2 wherein the pathogen is collected or removed from the second solvent stream.

35. (Canceled) The method according to claim 2 wherein substantially all of the pathogen is removed from the mixture.

36. (Canceled) The method according to claim 2 wherein the mixture comprises at least two types of pathogen and only one type is caused to move into the second solvent stream.

37. (Canceled) A compound and solvent stream substantially free from pathogens purified by the method according to claim 2.

38. (Canceled) The method according to claim 1 wherein the selective membrane has a molecular mass cut-off of at least about 3 kDa.

39. (Canceled) The method according to claim 1 further comprising the step of applying the electric potential across a third solvent stream, which third solvent stream is separated from a selected one of the first and second solvent streams by a second selective membrane, so as to cause the migration of at least a portion of at least one of the compound and the pathogen through the second selective membrane and into the third solvent stream.

40. (Canceled) The method according to claim 39 further comprising the step of applying the electric potential across a fourth solvent stream, which fourth solvent stream is

separated from the other of the first and second solvent streams by a third selective membrane, so as to cause the migration of at least a portion of at least one of the compound and the pathogen through the third selective membrane and into the fourth solvent stream.

41. (Canceled) The method according to claim 2 further comprising the step of applying the electric potential across a third solvent stream, which third solvent stream is separated from a selected one of the first and second solvent streams by a second selective membrane, so as to cause the migration of at least a portion of at least one of the compound and the pathogen through the second selective membrane and into the third solvent stream.

42. (Canceled) The method according to claim 41 further comprising the step of applying the electric potential across a fourth solvent stream, which fourth solvent stream is separated from the other of the first and second solvent streams by a third selective membrane, so as to cause the migration of at least a portion of at least one of the compound and the pathogen through the third selective membrane and into the fourth solvent stream.

43. (New) A method for removing pathogens from biological liquids, said biological liquids containing at least one pharmaceutically active molecule, said method comprising the steps of:

providing a biological liquid, wherein pathogens are potentially present, in an apparatus comprising an anode and a cathode and a separation means suitable for separating said pathogens from said pharmaceutically active molecule, said separation means being positioned between said anode and said cathode;

applying current between said anode and said cathode, thereby causing one of said pathogens or said pharmaceutically active molecules to pass said separation means, and recovering said pharmaceutically active molecule in a form being essentially free of pathogens.

44. (New) The method according to claim 1 wherein said separation means is a filtration means.

45. (New) The method according to claim 2 wherein said filtration means is an ultrafiltration membrane.

46. (New) The method according to claim 2 wherein said filtration means is a nanofiltration membrane.

47. (New) The method according to claim 1 wherein said pharmaceutically active molecule is a protein.

48. (New) The method according to claim 5 wherein said protein is a blood protein.

49. (New) The method according to claim 5 wherein said protein is smaller than said pathogen and said separation means allows passing of said protein but prevents passing of said pathogen.

50. (New) The method according to claim 1 wherein said separation means is a series of filters with different separation characteristics.

51. (New) The method according to claim 8 wherein said different filtration characteristics are caused by different cut-off values of the filters in said series of filters.

52. (New) The method according to claim 1 wherein said pathogens are selected from the group consisting of viruses, bacteria, prions, and combinations thereof.

53. (New) The method according to claim 9 wherein said cut-off values are selected to allow a separation between said pharmaceutically active molecule and aggregate of said molecule.

54. (New) An apparatus for removing pathogens from biological fluids, said biological fluids containing at least one pharmaceutically active molecule, said apparatus comprising:

a container for uptake of said biological liquid,

an anode, a cathode, and a separation means suitable for separating said pathogens from said pharmaceutically active molecule, said separation means being positioned between said anode and said cathode, and

a current supply and means for applying said current between said anode and said cathode.

CLEAN VERSION OF PENDING CLAIMS

1. A method of removing a pathogen from a mixture containing a compound and the pathogen, the method comprising:

- (a) placing the compound and pathogen in a first solvent stream, the first solvent stream being separated from a second solvent stream by a selective membrane having a defined pore size;
- (b) selecting a buffer for the first solvent stream having a required pH;
- (c) applying an electric potential across the first and second solvent streams, wherein the application of such electric potential causes movement of at least a portion of the compound through the membrane into the second solvent stream while the pathogen is substantially retained in the first solvent stream, or if entering the membrane, being substantially prevented from entering the second solvent stream and wherein substantially all transmembrane migration of the compound is initiated by application of the electric potential;
- (d) optionally, periodically stopping and reversing the electric potential to cause the movement of any pathogens having entered the membrane to move back into the first solvent stream, wherein substantially not causing any compounds that have entered the second solvent stream to re-enter the first solvent stream; and
- (e) maintaining step (c), and optional step (d) if used, until the second solvent stream contains the desired purity of the compound.

43. A method for removing pathogens from biological liquids, said biological liquids containing at least one pharmaceutically active molecule, said method comprising the steps of:

providing a biological liquid, wherein pathogens are potentially present, in an apparatus comprising an anode and a cathode and a separation means suitable for separating said pathogens from said pharmaceutically active molecule, said separation means being positioned between said anode and said cathode;

applying current between said anode and said cathode, thereby causing one of said pathogens or said pharmaceutically active molecules to pass said separation means, and

recovering said pharmaceutically active molecule in a form being essentially free of pathogens.

44. The method according to claim 1 wherein said separation means is a filtration means.

45. The method according to claim 2 wherein said filtration means is an ultrafiltration membrane.

46. The method according to claim 2 wherein said filtration means is a nanofiltration membrane.

47. The method according to claim 1 wherein said pharmaceutically active molecule is a protein.

48. The method according to claim 5 wherein said protein is a blood protein.

49. The method according to claim 5 wherein said protein is smaller than said pathogen and said separation means allows passing of said protein but prevents passing of said pathogen.

50. The method according to claim 1 wherein said separation means is a series of filters with different separation characteristics.

51. The method according to claim 8 wherein said different filtration characteristics are caused by different cut-off values of the filters in said series of filters.

52. The method according to claim 1 wherein said pathogens are selected from the group consisting of viruses, bacteria, prions, and combinations thereof.

53. The method according to claim 9 wherein said cut-off values are selected to allow a separation between said pharmaceutically active molecule and aggregate of said molecule.

54. An apparatus for removing pathogens from biological fluids, said biological fluids containing at least one pharmaceutically active molecule, said apparatus comprising:
a container for uptake of said biological liquid,
an anode, a cathode, and a separation means suitable for separating said pathogens from said pharmaceutically active molecule, said separation means being positioned between said anode and said cathode, and